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MCC = TAÛCELL



TAÛCELL
 ELEVATING
 STANDARDS
 AND TRUSTED
 LEGACY 😊



Nitika pharmaceutical specialities pvt ltd



Nitika pharma is a leading excipients manufacturing company and has built a strong reputation in pharmaceutical and allied sector. Nitika is pioneer in manufacturing spray dried MCC which is the largest used excipients in the oral dosage form. Nitika pharma has successfully developed 15 grades of MCC and is in the process of developing 15 co processed excipients. The most important value proposition of our MCC products is their ability to facilitate challenging and innovative formulations bringing to market. This dedication to quality and the ability to customize solution as per specific requirements are the key factors contributing to our success.

Happiness is.... Perfect, Customised Excipients.

www.nitikapharma.com

TABCELL

TABCELL is the product that reflects our commitment to excellence and sustainability. It emerges from the purest form of cellulose and is derived from the most sustainable natural source i.e. wood pulp.

This meticulous research effort underscores our dedication and thoughtfulness. TABCELL versatility spans various sectors, encompassing pharmaceuticals, food, nutraceuticals, and more, making it an ideal choice for a wide range of applications.



TABCELL Product application

1. Pharmaceutical Industry



TABCELL serves as an excellent excipient for solid dosage forms, providing numerous advantages for tablet formulations. It seamlessly integrates into various manufacturing processes, including DC compression, wet granulation, and dry granulation, ensuring compatibility regardless of the chosen method. Its exceptional properties also make it suitable for preparing pellets or beadlets through extrusion and spheronization techniques.

2. Nutraceutical/Food industry

TABCELL exceptional properties have made it a valuable asset in both the food and nutraceuticals industries. TABCELL has a unique position as a fat replacer & is particularly used in low fat ice creams



3. Personal care product



TABCELL serves as a versatile ingredient in various cosmetic formulations, including creams, lotions, and powders. It acts as a stabilizer, thickener, and binder, contributing to the texture, consistency, and performance of cosmetic products.



TABCELL DATA SHEET

Type	LOD	Bulk Density	Particle Size Distribution		
			D 10(μm)	D 50(μm)	D 90(μm)
101	NMT 6.0	0.24-0.36	<30	45-75	>110
102	NMT 6.0	0.28-0.35	<50	90-140	>170
103	NMT 3.0	0.26-0.34	<30	45-75	>110
105	NMT 5.0	0.35-0.44	<15	17-27	>35
112	NMT 1.5	0.28-0.34	<50	90-140	>170
113	NMT 1.5	0.27-0.34	<30	45-75	>110
200	NMT 6.0	0.29-0.39	<85	150-280	>310
301	NMT 6.0	0.34-0.45	<30	45-75	>110
302	NMT 6.0	0.35-0.46	<50	90-140	>170

TABCELL complies with the most current pharmacopeia edition, USP/NF EP and JP.

TABCELL MAPPING

- Original: 101 and 102
- Reduced moisture content: 103, 112, and 113
- Larger particle size: 200, 212
- Greater density: 301 and 302
- Decreased particle size: 105



TABCELL TUTORIAL :
Exploring different types and Applications

TABCELL 101 As a fine particle standard type, TABCELL 101 excel in providing outstanding tablet hardness, superior binder capacity; suitable for various pharmaceutical processes direct compression, wet granulation, spheronization and capsule filling	TABCELL 301/302 Particle size identical to TABCELL 101, offer denser composition, resulting in improved flowability and tablet weight uniformity. An excellent choice for smaller tablet and serve as reliable excipient in capsule filling.
TABCELL 102 A standard type with coarser particle size, offer notable advantages over 101, as it significantly enhances the flowability of fines.	TABCELL 113 A similar type to TABCELL 101, but with lower moisture content compared to 101& 103. TABCELL 113 is recommended for the protection of moisture sensitive active ingredient.
TABCELL 112 Stands out due to its lower moisture content (1.5%) making it preferred choice for API that are sensitive to moisture.	TABCELL 105 Finest particle size & highly compressible among MCC grade. Enhances tablet hardness in roller compaction & direct compression; Blends well with other coarse type for tailored flow & compression properties; ideal for chewable tablet, improving texture & compressibility.
TABCELL 200 Distinguished by its large particle size, resulting in enhanced flowability; specially employed to mitigate weight variation & enhance content uniformity in both DC & Wet granulation formulation.	TABCELL 103 Similar type to 101 but with lower moisture content. Recommended for water sensitive active ingredient.



TABCELL LN Grade (Microcrystalline cellulose)

Microcrystalline Cellulose is a commonly used high-dose filler. In response to industry demands and our commitment to the highest standards, we have developed LN-grade Microcrystalline Cellulose. Each batch is rigorously tested for Nitrate and Nitrite, here are the available grades.

Microcrystalline Cellulose (MCC) is produced from plant-derived β -cellulose via aqueous mineral-acid hydrolysis, neutralization, and extensive washing—an inherently water-intensive sequence of unit operations. Because MCC typically constitutes the highest-dose excipient in solid oral dosage forms, even low background levels of nitrite/nitrate originating from raw materials or utilities can disproportionately determine the excipient-derived nitrite burden of the finished product. Reducing this burden at the source is therefore a critical element of contemporary nitrosamine-control strategies.

Lhasa Limited has conducted in-depth studies to evaluate the nitrite levels in formulations containing Microcrystalline Cellulose (MCC), key observations are as below; • The impact of MCC on the final nitrosamine content is the highest among all studied excipients, primarily due to its higher usage level in formulations. • Nitrite levels vary among different manufacturers of MCC. • There is batch-to-batch variation in the nitrite levels from the same supplier.

TABCELL LN (Microcrystalline cellulose)

Considering the significant impact of Microcrystalline Cellulose (MCC) on nitrite content in formulations, Nitika Pharma has developed a low nitrite grade MCC with a customized manufacturing process. This innovative grade is backed by a validated ion chromatography (IC) method to ensure precise nitrite measurement. Our rigorous raw material control and quality assurance protocols guarantee consistent low nitrite levels across multiple batches, ensuring formulation safety and compliance. The results of various batches are presented below, demonstrating the stability and reliability of our MCC in maintaining low nitrite content.

Grade	Nitrite	Nitrate	Application
TABCELL 101 LN	<0.05 ppm	<1 ppm	High shear wet granulation, Extrusion, Spheronization
TABCELL 102 LN	<0.05 ppm	<1 ppm	Direct compression, Dry Granulation
TABCELL 112 LN	<0.05 ppm	<1 ppm	Low moisture grade for direct compression, Dry granulation
TABCELL 200LN	<0.05 ppm	<1 ppm	Direct Compression, dry Granulation.

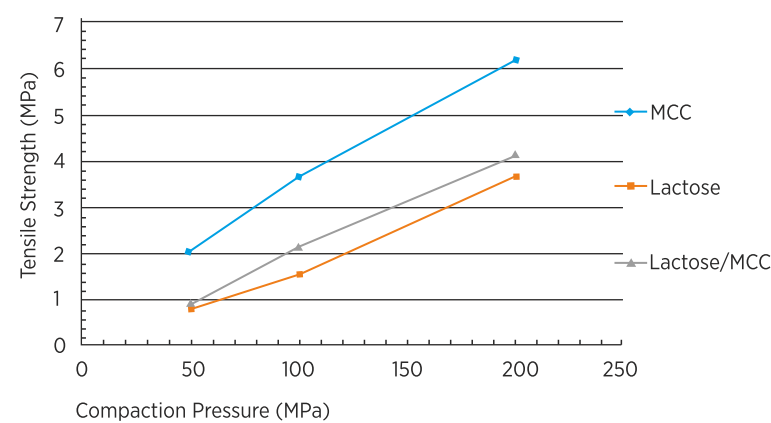
High Performance Ion Chromatography System, For in-house nitrite testing for reliable results



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WHY TABCELL ?

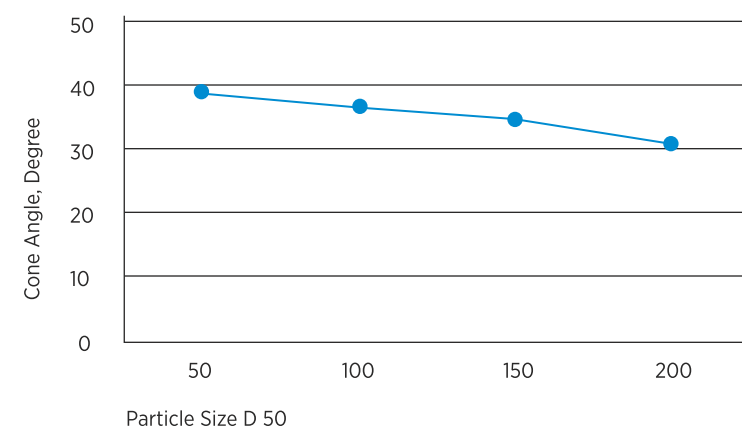
•Tabcell stands out as a robust dry binder offering remarkable dilution potential. Its exceptional physical attributes, coupled with its multifunctionality, position it as the preferred choice for tablet formulation compared to other common filler-binders available in the market. The accompanying diagram illustrates the relative compactability of these representative filler-binders. When subjected to identical compression forces, Microcrystalline Cellulose showcases unparalleled compactability. Even at lower usage levels than alternative tablet components, it yields equivalent or superior tablet hardness results.



PARTICLES SIZE V/S FLOWABILITY

The connection between particle size and flowability is clear: larger particles generally result in improved flowability. Fluctuations in powder flow during production directly impact product quality, influencing factors like weight consistency and uniformity of content. Additionally, flow has a direct bearing on manufacturing efficiency, affecting processes such as blending speed and tablet production rate

Powder Flow (Angle of repose)



CONTROLLING OF BLACK PARTICLES

•Nitika is dedicated to ensuring the consistent quality of our products across all batches. The presence of black specks has long been a significant worry for pharmaceutical manufacturers. Recognizing the industry's demand for materials with minimal black speck occurrences, Nitika has taken steps to replace traditional and labor-intensive visual inspections with a reliable scientific approach. Through cutting-edge instruments and trend analysis, we have successfully maintained consistently low black speck counts in every production lot.

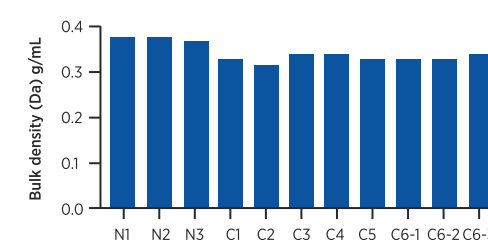
CASE STUDY - PHASE I

ICT conducted a comparative study of Nitika's TABCELL Microcrystalline Cellulose against five global manufacturers using the SeDeM diagram expert system for pharmaceutical characterization.

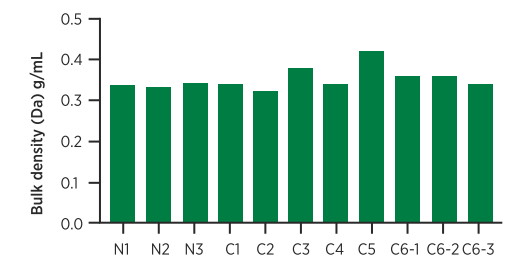
Phase 1: Evaluation of physical properties including Bulk Density, Tapped Density, Inter-particle Porosity, Carr Index, etc

N1/N2/N3 - Tabcell
C1/C2/C3/C4/C5/C6-1/C6-2/C6-3 - MCC from competitors

Bulk density – MCC 101 /102

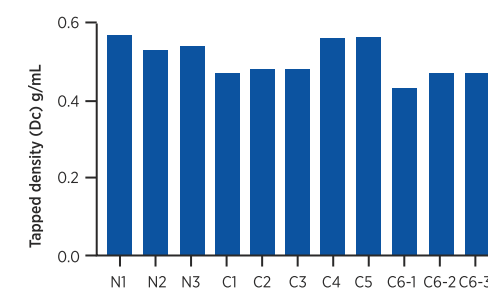


Tabcell 101 exhibits a higher bulk density compared to most other microcrystalline cellulose brands, indicating its robust quality and uniformity.

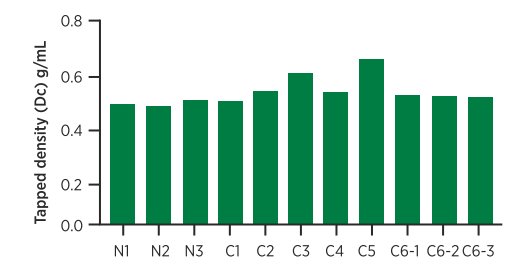


From the graph, it was observed that Tabcell 102 shows a consistent bulk density similar to other microcrystalline cellulose brands.

Tapped density – MCC 101 /102

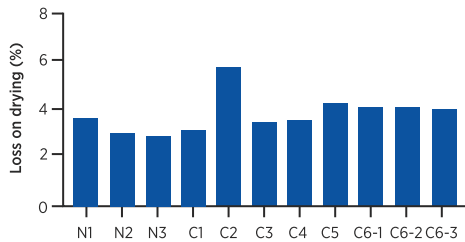


Tapped density – MCC 101 /102 The tapped density of Tabcell 101 grades shows consistent and competitive performance compared to other MCC brands.

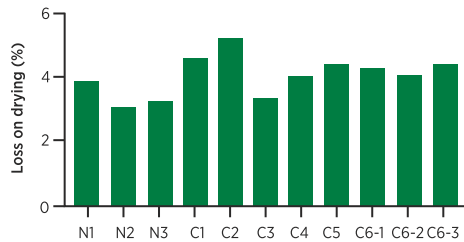


Tabcell 102-2 demonstrates balanced and reliable tapped density, ensuring consistent bulk properties for formulation uniformity.

Loss on drying – MCC 101/102

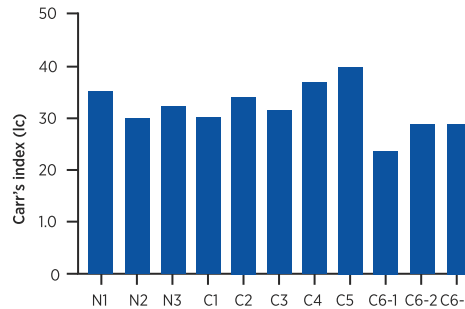


Tabcell 101 consistently shows lower loss on drying values compared to other MCC brands. Tabcell 101's moisture content is stable, indicating reliable quality across batches

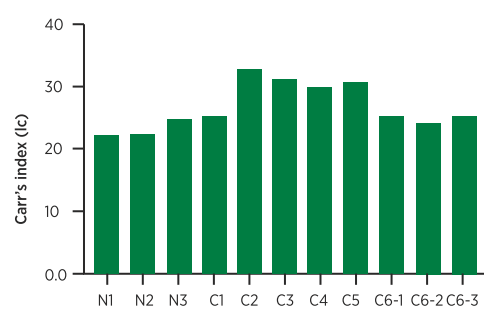


Tabcell 102 demonstrates consistent low loss on drying values, with results ranging from 3.17% to 3.97%.

Carr's Index – MCC 101/102

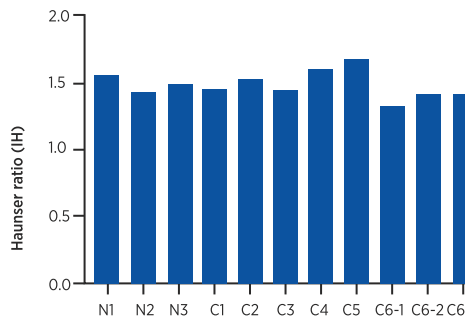


Tabcell101's Carr's Index values align closely with competitors.

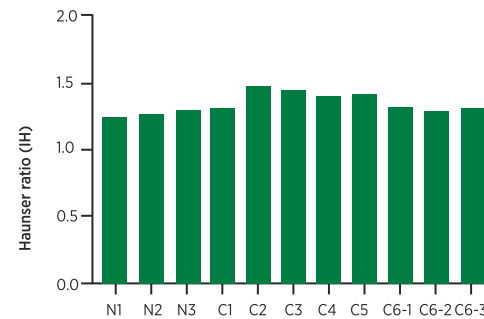


The graph shows that Tabcell 102 grades consistently achieve Carr's Index values below 26, reflecting superior flowability compared to competitors.

Hausner Ratio – MCC 101/102



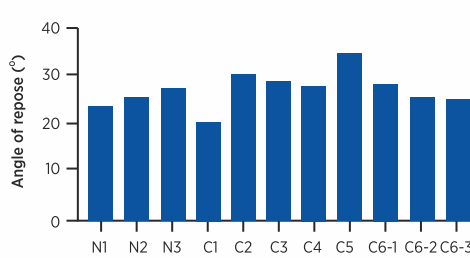
Tabcell 101 performs similarly to competitors with its Hausner ratio values.



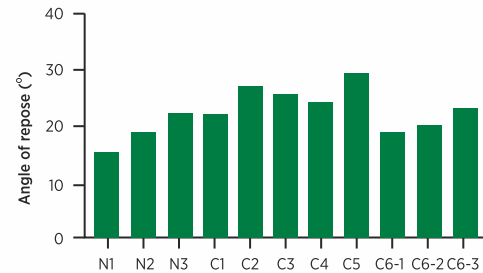
The graph shows that Tabcell 102 grades, with Hausner ratios ranging from 1.30 to 1.35, demonstrate better flowability, falling within the "fair" to "good" range compared to other MCC brands.



Angle of Repose – MCC 101/102

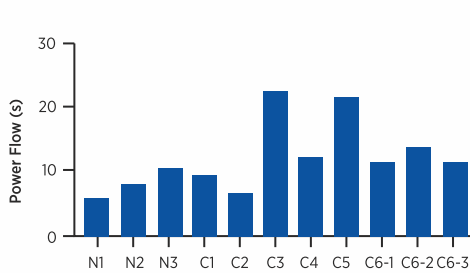


The Tabcell 101 series exhibits lower angles of repose (24.15° to 27.82°), indicating better flow properties compared to other brands, which is essential for efficient pharmaceutical processing.

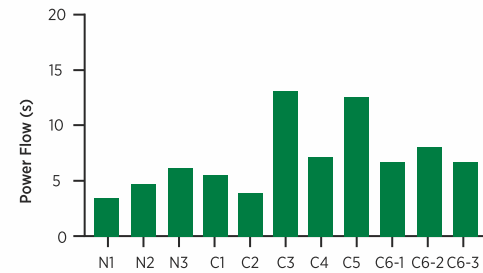


The Tabcell 102 series shows significantly lower angles of repose (15.41° to 22.36°), indicating excellent flow properties compared to competition

Powder Flow – MCC 101/102



Tabcell 101 powders exhibit faster powder flow compared to other brands indicating superior flowability for efficient pharmaceutical processing.



Tabcell 102 shows consistent and faster powder flow times across different grades, making it a reliable choice for high-performance pharmaceutical formulations.

CONCLUSION OF CASE STUDY - PHASE I

Based on the analysis, it appears that Tabcell 102-1 and Tabcell 102-2 exhibit powder traits closely resembling with global players indicating a high degree of similarity among these variants.

Tabcell 101-1, Tabcell 101-2, and Tabcell 101-3 showcase markedly better powder characteristics compared to all other MCC 101 grade manufacturers

CASE STUDY - PHASE II

A comprehensive study conducted by the Indian Chemical Institute, Mumbai, utilizing the SeDeM Methodology, assessed various tablet parameters for Metformin and Ibuprofen (250mg and 500mg tablet).

The study specifically evaluated critical tablet characteristics such as compression, drug release, weight variation, hardness, disintegration time, thickness, and friability, using Tabcell® (MCC manufactured by Nitika) in comparison to competitor MCC grades.

CONCLUSION OF CASE STUDY - PHASE II

Tabcell® 102 and Tabcell® 101 exhibit nearly identical IGC values, yet Tabcell® 102 stands out with the highest flowability across all grades, making it the preferred choice for tableting of formulations with poor flow properties.

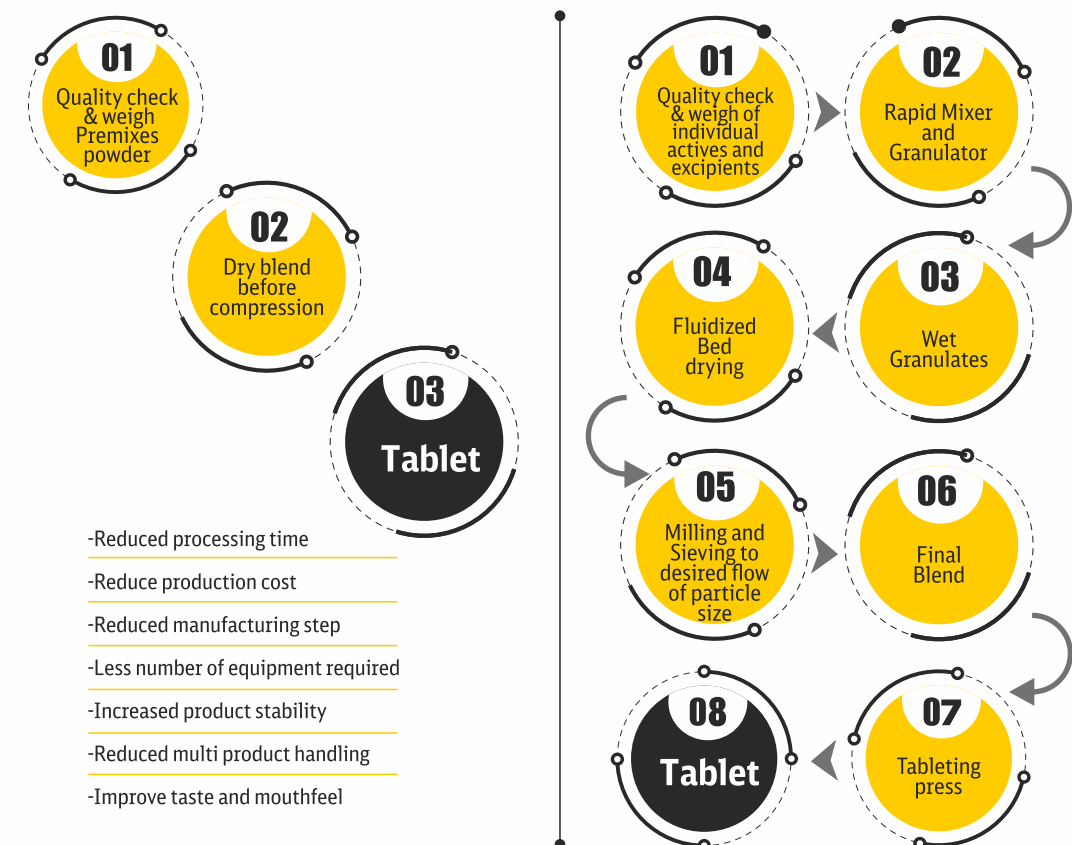
The superior flow characteristics of Tabcell® 102 make it the most suitable grade for direct compression applications, as it enhances powder handling, improves tablet uniformity, and facilitates efficient manufacturing processes, providing optimal performance for formulations requiring enhanced flowability.

Why CO-TABCELL ?

- With the advancement of tablet manufacturing process, the demand of excipients with improved functionalities, mainly in terms of flow and compression properties, has increased.
- Co-processed excipients are a mixture of two or more existing excipients at sub particle level, offer substantial benefits of the incorporated excipients and minimize their drawbacks. These multipurpose excipients have dramatically reduced the number of incorporating excipients in the tablet.

Co-Process / Premixes Processing

Conventional processing



Co processed Excipien	Utilization
MCC+MANNITOL	Enhances wet granulation
MCC+STARCH	Binder & filler
MCC+LACTOSE+STARCH	Suspension & emulsion
MCC+MALTODEXTRIN	Improve solubility& flow of powder
MCC+NaCMC(RC-591)	Thickner, stabilizer & emulsifier
MCC+NaCMC(RC-581)	Improve stability & texture
MCC+NaCMC(CL-611)	Food additive & pharmaceutical excipient
MCC+SiO2	Binder, disintegrant, diluent
MCC+Calcium Phosphate	Tablet hardness enhancer, sustain release
MCC+GUAR GUM	Viscosity enhancer, dietary supplement
MCC+SODIUM ALGINATE	Binder,disintegrant & viscosity enhancer

1. MCC and Mannitol

A co-processing excipients was developed by spray-drying a slurry of Microcrystalline Cellulose and mannitol, resulting in the formation of spherical particles. This composition exhibited enhanced compatibility, reduced sensitivity to lubrication, and improved ejection characteristics when compared to both the physical mixture of MCC and mannitol, as well as their individual components.

2. MCC and Lactose

This innovation, blended with pearlitol in various ratios, offers optimal compressibility and fast disintegration. It's the key ingredient used to create paracetamol orally disintegrating tablets, showcasing our commitment to pharmaceutical excellence.

3. MCC & Starch

A co-processed excipients that combines the qualities of rice starch and MCC. Through the innovative method of spray-drying, composite particles of rice starch and MCC have been meticulously crafted, forming a highly efficient directly compressible excipient. Notably, its compressibility surpasses that of commercial spray-dried rice starch, co-processed lactose and microcrystalline cellulose, as well as agglomerated lactose. Its compressibility remains slightly lower than that of microcrystalline cellulose.

4. MCC, Lactose & Starch

Through the wet granulation process, a synergistic blend of lactose monohydrate, MCC, and cornstarch is transformed into co-processed micro-granules. This final product boasts exceptional binding capabilities, rapid disintegration times, and enhanced flow properties, making it a truly exceptional outcome.



5. MCC & Maltodextrin

A combination of MCC and maltodextrin is skillfully blended and then subjected to spray drying. This resulting dispersion exhibits valuable stabilizing properties, rendering it suitable for applications in both the food and cosmetic industries.

6. MCC & Sod.CMC (RC 591)

The co-processing of MCC and Sod. CMC (RC-591) offers technical advantages such as optimized particle packing for improved tablet hardness and reduced friability. Additionally, the synergy between these excipients can enhance drug dissolution rates through controlled wettability and swelling properties, making it valuable for enhancing pharmaceutical formulations.

7. MCC & Sod.CMC(RC-581)

The co-processing of MCC and Sod.CMC (RC-581) yields enhanced tablet cohesion and disintegration. This combination also enables controlled drug release, providing a versatile solution for achieving desired pharmaceutical formulation outcomes.

8. MCC & Sod.CMC(CL-611)

The blend of MCC and Sod.CMC (CL-611) serves as a multifunctional ingredient in both food and pharmaceutical applications. This combination offers improved texture and mouthfeel in food products, while in pharmaceuticals, it enhances tablet disintegration and aids controlled drug release, making it a versatile choice for various formulations.

9. MCC & Silicone Dioxide

This novel excipient boasts exceptional free-flowing characteristics, rapid disintegration properties, and enhanced compressibility compared to standard commercially available MCC.

10. MCC & DCPA

By combining aqueous slurries of microcrystalline cellulose and calcium phosphate, followed by spray drying, finely textured particulate products are formed. The ultimate outcome showcases elevated compatibility, outperforming conventional dry physical blends of identical constituents.

11. MCC & guar Gum

A co-processed excipients for chewable tablets by meticulously blending an aqueous mixture of MCC and guar gum using high shear forces at ambient temperature. The resulting uniform dispersion is subjected to spray drying, yielding an aggregate powder with predominantly spherical particles. This excipients offers enhanced compressibility, a pleasing mouthfeel, and effectively minimizes issues related to tooth packing.

12. MCC & sodium Alginate

MCC and sodium alginate collaborate as a wet granulation binder-type excipients. The process involves creating a consistent aqueous slurry of the two components, followed by spray drying to yield granular particles.